

REMARKS

Favorable reconsideration of this application, in light of the preceding amendments and following remarks, is respectfully requested.

Claims 1 and 3-14 are pending in this application.

Rejections under 35 U.S.C. § 103

Claims 1 and 3-14 stand rejected under 35 U.S.C. § 103(a) as being anticipated by WO 03/040878 to R. Bharat Rao ("Rao"). Applicants respectfully traverse this rejection for the reasons detailed below.

On page 4 of the current office action the Examiner states:

Rao does not explicitly teach a method wherein determining if patient data associated with a patient has changed, the patient data being stored in a data processing system and associated with a plurality patient; checking the patient data with respect to the selection criteria automatically if the determining step determines the patient data has changed; selecting the patient associated with the patient data as a potential participant if the selection criteria are met; and reporting the selected patient as a potential participant. It would have been obvious to one of ordinary skill in the art at the time the invention to expand the method of Rao. One of ordinary skill in the art at the time of the invention would have been motivated to expand the method of Rao in this way since all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known systems/methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. Emphasis original.

The Examiner is reminded of the requirement for reliance on common knowledge in the art or "well known" prior art as described in MPEP 2144.03. MPEP 2144.03 states:

Official notice without documentary evidence to support an examiner's conclusion is permissible only in some circumstances. While "official notice" may be relied on, **these circumstances should be rare when an application is under final rejection or action under 37 CFR 1.113.**

Official notice unsupported by documentary evidence should only be taken by the examiner where the facts asserted to be well-known, or to be common knowledge in the art are **capable of instant and unquestionable demonstration as being well-known**. As noted by the court in *In re Ahlert*, 424 F.2d 1088, 1091, 165 USPQ 418, 420 (CCPA 1970), the notice of facts beyond the record which may be taken by the examiner must be "capable of such instant and unquestionable demonstration as to defy dispute" (citing *In re Knapp Monarch Co.*, 296 F.2d 230, 132 USPQ 6 (CCPA 1961)). In *Ahlert*, the court held that the Board properly took judicial notice that "it is old to adjust intensity of a flame in accordance with the heat requirement." See also *In re Fox*, 471 F.2d 1405, 1407, 176 USPQ 340, 341 (CCPA 1973) (the court took "judicial notice of the fact that tape recorders commonly erase tape automatically when new 'audio information' is recorded on a tape which already has a recording on it"). In appropriate circumstances, it might not be unreasonable to take official notice of the fact that it is desirable to make something faster, cheaper, better, or stronger without the specific support of documentary evidence. Furthermore, it might not be unreasonable for the examiner in a first Office action to take official notice of facts by asserting that certain limitations in a dependent claim are old and well known expedients in the art without the support of documentary evidence provided the facts so noticed are of notorious character and serve only to "fill in the gaps" which might exist in the evidentiary showing made by the examiner to support a particular ground of rejection. *In re Zurko*, 258 F.3d 1379, 1385, 59 USPQ2d 1693, 1697 (Fed. Cir. 2001); *Ahlert*, 424 F.2d at 1092, 165 USPQ at 421.

As the Examiner knows, this action is final. As stated above, "official notice" should be rarely used if an action is final. Further, the limitations the Examiner states are "obvious to one of ordinary skill in the art," are not capable of instant and unquestionable demonstration as being well-known.

Further, MPEP 2144.03 goes on to state:

In certain older cases, official notice has been taken of a fact that is asserted to be "common knowledge" without specific reliance on documentary evidence where the fact noticed was readily verifiable, such as when other references of record supported the noticed fact, or where there was nothing of record to contradict it. See *In re Soli*, 317 F.2d 941, 945-46, 137 USPQ 797, 800 (CCPA 1963) (accepting the examiner's assertion that the use of "a control is standard procedure throughout the entire field of bacteriology" because it was readily verifiable and disclosed in references of record not cited by the Office); *In re Chevenard*, 139 F.2d 711, 713, 60 USPQ 239, 241 (CCPA 1943) (accepting the examiner's finding that a brief heating at a higher temperature was the equivalent of a longer heating at a lower temperature where there was nothing in the

record to indicate the contrary and where the applicant never demanded that the examiner produce evidence to support his statement). If such notice is taken, the basis for such reasoning must be set forth explicitly. The examiner must provide specific factual findings predicated on sound technical and scientific reasoning to support his or her conclusion of common knowledge. See *Soli*, 317 F.2d at 946, 37 USPQ at 801; *Chevenard*, 139 F.2d at 713, 60 USPQ at 241. **The applicant should be presented with the explicit basis on which the examiner regards the matter as subject to official notice** ~~so as to adequately traverse the rejection~~ *in the next reply after the Office action in which the common knowledge statement was made.* Emphasis added.

Applicants submit the Examiner has not provided the Applicant with an “explicit basis on which the examiner regards the matter as subject to official notice.”

Further, MPEP 2144.03 goes on to state:

To adequately traverse such a finding, an applicant must specifically point out the supposed errors in the examiner's action, which would include stating why the noticed fact is not considered to be common knowledge or well-known in the art.

Applicants traverse the Examiner's findings at least because the action is final, the limitations the Examiner states are obvious to one of ordinary skill in the art are not capable of instant and unquestionable demonstration as being well-known, and the Examiner has not provided the Applicant with an explicit basis on which the examiner regards the matter as subject to official notice. Further, Applicants submit that if one skilled in the art were to follow the teaching according to Rao in order to include current patients in studies, one skilled in the art would have to continuously send new requests at predetermined points in time to the database, requesting that a new check of all patients be again be carried out, e.g. in a narrow time grid.. Only in this way would it be possible to select patients for studies for which the data have

changed since the preceding check. This method would result in an extremely involved operation.

Applicants submit the reliance on common knowledge in the art or "well known" prior art by the Examiner in making the current rejection is improper. Therefore, Applicants respectfully request the rejection to be withdrawn. In the alternative, Applicants request the Examiner to provide specific documentary evidence to support the Examiner's conclusion that the aforementioned limitations would have been known to one skilled in the art at the time of the invention.

For at least the reasons described above, Rao does not teach or fairly suggest each and every limitation of claim 1. Because Rao does not teach or fairly suggest each and every limitation of claim 1, Rao does not anticipate or render claim 1 obvious. Claims 3-14 are patentable at least by virtue of their dependency from claim 1.

The Applicants, therefore, respectfully request reconsideration and withdrawal of the rejection to claims 1 and 3-14 under 35 U.S.C. § 103(a).

CONCLUSION

In view of the above remarks and amendments, the Applicants respectfully submit that each of the pending objections and rejections has been addressed and overcome, placing the present application in condition for allowance. A notice to that effect is respectfully requested. If the Examiner believes that personal communication will expedite prosecution of this application, the Examiner is invited to contact the undersigned.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact the telephone number of the undersigned below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 08-0750 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

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By


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